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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

DAVIS, DEBORAH A

ART UNIT PAPER NUMBER

1641

DATE MAILED: 02/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/024,258

Applicant(s)

SCHELP ET AL.

Examiner

Deborah A. Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 23-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☒ Claim(s) 18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant acknowledges that the restriction of the previous Office Action was made final but requests that the examiner consider rejoining Groups I and II if Group I is found to be allowable. In response, it is not appropriate to rejoin two patentably distinct methods. If the method of Group I is found to be allowable, it does not necessitate the patentability of Group II. ***Therefore, the restriction of Groups I and II are deemed proper and made final.***

Priority

2. The examiner acknowledges the receipt of priority document.

Information Disclosure Statement

3. Applicant has submitted a copy of the postcard receipt with the USPTO acknowledgement of receipt of the PTO-1449 form and its 31 documents cited therein on April 3, 2002. However, the examiner has not to this date received these documents and therefore they will not be considered.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-4, and 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Pekka Palomaki (Journal of Immunological Methods, Vol. 145, (1991) pages 55-63).

The claims are broadly drawn to a method for detecting an analyte A in a sample comprising incubation of a sample with an analyte binding partner R1 associated with a solid support, R2 associated with a label L1 and R3 associated with label L2 wherein saturation of analyte A-binding sites of the R2 binding partner takes place at a higher analyte A concentration at a later time in the incubation than does saturation of analyte A-binding sites of the R3 binding partner and determining and L1-dependent measurement signal at a different time from and L2-dependent measurement signal or an L1 plus L2-dependent measurement signal.

The reference of Pekka Palomaki teaches a enzyme immunoassay (EIA) for the detection of hepatitis B surface antigen (HBsAg) in human serum or plasma using a monoclonal antibody Mab1 coated to a solid phase (R1 + solid phase) and incubated with HbsAg and a peroxidase labeled polyclonal antibody (HRP-Pab), which the examiner considers to be (R2 + L1) and a second peroxidase labeled monoclonal antibody Mab2 (HRP-Mab2), which the examiner considers to be (R3 + L2) to form sandwich complexes (see abstract and page 58, column 1, paragraphs 1-3). Absorbances at 450 nm were measured using a microtitre plate reader (page 57, column 2, paragraph 5), which the examiner interprets to be L1 and L2 measurements. The reference also teaches a two one step EIA that a separate measurement was taken at optimal concentration when the HRP-Pab-HbsAg was used alone or simultaneous

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with diluted HRP-Mab2-HbsAg in the assay (page 58, column 2, paragraph 2). With respect to the saturation of analyte A-binding sites of the binding partner R2 taking place at a higher analyte A concentration than that of R3 is inherent to the HbsAg assay. Since the reference of Palomaki teaches the use of Polyclonal and Monoclonal antibodies to detect HbsAg, the saturation of the polyclonal antibodies binding sites would take place at a higher analyte concentration than that of the monoclonal antibodies because polyclonals are less specific than that of monoclonals and therefore would require more of the analyte to saturate its binding sites. The reference teaches that colour development was allowed to proceed in the dark for 30 minutes at room temperature (page 57, column 2, paragraph 5), which is qualitative measurement. The assay method can be a one or two step sandwich, (page 57, column 2, paragraph 4) which the examiner interprets as being heterogeneous or homogeneous. Binding partners R1 and R3 are the same binding partners, which are monoclonal Mab1 and Mab2 (see abstract).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 5,6, and 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pekka Palomaki in view of Marquardt et al (USP#6,610,494).

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The teachings of Palomaki are set forth above but sole difference appears to be that it does not teach an additional labeling system such as an XY binding pair.

However, the reference of Marquardt et al teaches an XY binding pair such as biotin-avidin (or streptavidin) labeling system that is used for indirect measurement of an analyte by measuring the label (column 7, lines 35-50). With respect to the relationship of the L1-dependent measurement signals determined at time T1 and the L2 – dependent measurement signal being determined at time T2, with T1 being earlier than T2 is taught by the primary reference of Palomaki. Palomaki teaches an embodiment wherein the sample is contacted with (R2) associated with label L1 and (R1) associated with a solid phase is incubated to form a complex sandwich and measured. This is the first measurement signal that represents time T1. An additional entity (R3) associated with label L3 is added to the mixture in an amount to reduce the hook effect (page 57, column 2 paragraphs 1-4). The examiner interprets this as the second measurement signal time T2, which measurement is later than that of T1 which makes T1 measurement earlier than that of T2.

It would have been obvious to one of ordinary skill in the art to include the use of an XY binding system as in avidin-biotin or (streptavidin) because they are stable under the conditions of an assay, are specific and have low background values that do not interfere with the assay. One would be motivated to use this system because they give the assay greater sensitivity.

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8. Claims 10-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pekka Palomaki et al in view of a second reference by Cragle (USP#4,590,169).

The teaching of Pekka Palomaki is set forth above, but is silent with respect to the teachings of a suspendable solid phase.

However, the reference of Cragle teaches that binding entities use particles for direct particle agglutination assays, wherein the particles become aggregated if the antigen is in the sample and this protocol can be performed in one step.

It would have been obvious to one of ordinary skill in the art to modify the reference of Pekka Palomaki to include the use of suspendable beads in an assay system taught by Cragle because they are useful in agglutination assays. One of ordinary skill would be motivated to do so because particle agglutination can be performed in a one step, eliminating the need for separation of reagents.

9. Claims 16-17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pekka Palomaki in view of Pitner et al (USP#5,641,629).

The teaching of Pekka Palomaki are set forth above, but is silent with respect to energy transfer.

However, the reference of Pitner et al teaches that energy transfer techniques offers a sensitive and simple method of measuring the binding of specific analytes or target molecules. The method permits qualitative and quantitative binding measurements (column 4, lines 58-67).

Therefore, it would have been obvious to one of ordinary skill in the art to use energy transfer techniques as taught by Pitner et al because of its sensitivity and simplicity in measuring of analytes.

Response to Arguments

10. Applicant's arguments filed October 31, 2005 have been fully considered and found to be persuasive:

Applicant's arguments, with respect to the argument that examiner's conclusion of the saturation of L-Aba in the '6651 patent occurs at a higher analyte A concentration than that of L-Abc is erroneous have been found to be persuasive. Applicant further argues that the '661 patent teaches that L-Aba has a higher affinity constant than L-Abc and directs the examiner attention to col. 3, lines 34-36. Applicant contends that one skilled in the art would understand that the higher the affinity of an antibody for an antigen, i.e. the higher the affinity constant, then the lower the concentration of antigen is necessary for 50% of antigen to bind to the antibody. Thus, applicant contends, that the saturation of L-Aba would take place at a lower concentration of antigen, than its counterpart, L-Abc, contrary to the Examiner's contention that the saturation of L-Aba takes place at a higher concentration of the antigen. Therefore, with respect to the rejection(s) of claim(s) 1-4, 7-12 and 16 under 102(b) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. **However, upon further consideration, a new ground(s) of rejection is made above.**

Conclusion

Allowable Subject Matter

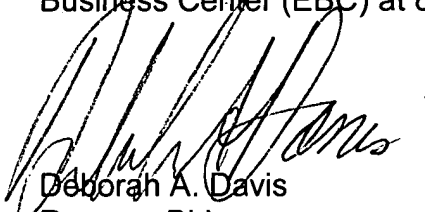
11. Claim 18 is allowed.
12. Claim 18 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
13. The following is a statement of reasons for the indication of allowable subject matter: The prior art neither teaches nor suggests a signal forming system that involves photosensitizers associated with microparticles and chemiluminescent substances associated with microparticles..

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A. Davis whose telephone number is (571) 272-0818. The examiner can normally be reached on 8-5 Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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January 30, 2006



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02/03/06